DTSC Green Ribbon Science Panel

April 23-24, 2019

Background Document

This document provides a brief background on topics to be discussed at the April 2019 meeting of the Department of Toxic Substance Control's Green Ribbon Science Panel (GRSP). Some topics have additional supplemental documents that will also be made available. The topics outlined below are focused on supporting the implementation of the Safer Consumer Products (SCP) regulations.

Topic 1. Alternatives Analysis Threshold Determination

Topic Summary

The Safer Consumer Product regulations allow DTSC to set an Alternatives Analysis Threshold (AAT) when proposing a Priority Product. Manufacturers whose products contain the Chemical of Concern at concentrations below the AAT must notify DTSC that they sell the product and provide evidence that their product meets the AAT, but do not have to comply with the Alternative Analysis requirements of Article 5 in SCP's regulations.

DTSC can elect to establish an AAT for a specific Priority Product, but in most cases is not required to do so. In the case of an unintentionally added ingredient, an AAT is required but is assumed to be equivalent to the Practical Quantitation Limit (PQL) unless DTSC elects to set an AAT above that value. The PQL must be specified by DTSC and is loosely defined in the SCP regulations as the level at which a contaminant can be reliably measured by most laboratories using routine laboratory procedures.

DTSC has not yet opted to set an AAT for a proposed or adopted Priority Product. However, in our product chemical prioritization research, we have been investigating the presence of the contaminant 1,4-dioxane in personal care and cleaning products. 1,4-dioxane is a contaminant associated with production of the ethoxylated surfactants often used in these products. Despite toxicity concerns, companies have struggled to completely remove 1,4-dioxane from their products. 1,4-dioxane is also analytically challenging, and detection limits are constantly evolving as analytical methodologies improve. If DTSC ever decides to propose a Priority Product containing 1,4-dioxane, a PQL or an AAT would also have to be proposed because 1,4-dioxane is a contaminant. Additionally, recent feedback from the Personal Care Products Council recommends that DTSC set an AAT for toluene in our recently proposed Nail Products containing Toluene Priority Product.

While an AAT is not meant to indicate a certain level of safety or a lack of risk, the very act of defining a value below which manufactures are not required to take any action to evaluate the safety of the chemical in the product holds implications that DTSC would need to consider before releasing a

proposal. This brings up a number of questions on both PQLs and AATs that we think the Panel will be able to advise us on.

Two illustrative cases will be used to shape the discussion and highlight how others have dealt with similar issues relevant to determining PQLs and AATs. The first case will examine the Office of Environmental Health Hazard Assessment's (OEHHA) consideration of Safe Use Determination (SUD) requests. SUD requests are initiated when a business asks the agency to determine if exposure to a chemical from a product is at or below the Safe Harbor Level indicated as a part of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65). If a SUD request is granted by OEHHA, a business does not have to provide the chemical exposure warnings for those specific applications. Dr. Martha Sandy of OEHHA will provide a brief presentation on how OEHHA conducts a SUD evaluation and any aspects of this process that may be useful for DTSC in setting an AAT. This presentation, anchored in a risk assessment methodology, also serves as an example of the type of implications stakeholders are used to when an agency sets (or approves) a specific threshold value. This is particularly important to understand given that, in contrast to SUD determinations and many other regulatory approaches, SCP is not risk-based and an AAT is not a safety standard.

The second real-world case comes from Seventh Generation, a household and personal care products company focused on creating products that protect humans and the environment. From 2008-2010 the company worked with their surfactant suppliers to reduce levels of 1,4-dioxane in the surfactant ingredients that are added to their laundry and dish detergents to below their limit of detection (0.5 ppm). SCP staff will present the background of this case study to provide some context about the difficulties that companies could face in removing a contaminant from their product. The analytical challenges of 1,4-dioxane become especially relevant in this case. While the company encountered a limit of detection of 0.5 ppm when conducting their work, newer analytical methodologies are able to detect 1,4-dioxane at concentrations that are an order of magnitude lower. This reemphasizes the importance and challenge of setting a PQL if DTSC elected to not set an AAT.

Questions to Panel

- What should SCP take in to consideration when setting an AAT?
- How do we ensure protection against hazardous chemicals in the face of practical constraints (e.g. feasibility)?
- What are the consequences of setting an AAT from a technical perspective and for stakeholder's perception of the program? How do we ensure that an AAT is not confused with a safety assessment such as a SUD?
- Should SCP set AATs at all given the potential implications that there is an acceptable level of a hazardous chemical and implies a risk assessment calculation and mindset? If not, how would you recommend that we determine the PQL?

Supporting Documents

- 3 - Pertinent Sections of the Safer Consumer Products Regulations & Final Statement of Reasons

- 4 - PCPC Comments in Listing of Toluene in Nail Products
- 5 - OEHHA SUDs Fact Sheet
- 6 - OEHHA SUD Requests Essential Elements Presentation
- 7 - Seventh Generation Case Study
- 8 - Guest Speaker Profile for Dr. Martha Sandy, OEHHA

Topic 2. Determining Metrics for the SCP Program

Topic Summary

There is a vital need to establish metrics to convey and measure the successes, values, and efficacy of the SCP program. These metrics should be used to hold SCP accountable to the public and state legislature. However, choosing and evaluating the appropriate metrics is difficult. For example, the data we seek might not be available, or methods to accurately collect and quantify this data may not exist. Additionally, as Pollution Prevention programs are keenly aware, it is hard to measure something that *doesn't* happen or something that's been avoided. SCP's preventive nature has parallels to this historical Pollution Prevention dilemma. It is important to determine which metrics to use now so that we can collect relevant baseline data. It is also necessary to define what outcomes demonstrate program effectiveness and choose the appropriate metrics to use to track those outcomes over time.

To frame the discussion, Karl Palmer from SCP will present some of the historical challenges associated with measuring the success of Pollution Prevention programs. GRSP member Dr. Megan Schwarzman will present her research to define metrics that help to quantify the efficacy of OEHHA's Prop 65 program. SCP has also provided some preliminary ideas of metric options in Supporting Document 9. These talks will set the stage for a discussion on the metrics most applicable and relevant for the SCP Program. SCP will evaluate the proposed options for measuring our efficacy.

Questions to Panel

- Which metrics are most applicable, achievable, and informative for SCP?
- What metrics are used in similar programs (WA Dept of Ecology, EPA's Safer Choice, Massachusetts TURI)?
- Which metrics are currently available and obtainable; which ones are promising, but need further research to be useable?
- Are there agencies, organizations, or researchers we should collaborate with to obtain the necessary metric data?
- What challenges do you envision for SCP as we work to establish metrics?
- How can we best convey success to the public and legislators?

Supporting Documents

- 9 - SCP Metric Ideas

Topic 3. Chemical Mixtures Evaluation

Topic Summary

Humans and wildlife are constantly exposed to chemical mixtures from a multitude of sources, including consumer products. Although an increasing number of studies have been conducted to understand the exposure and toxicity of chemical mixtures, the potential adverse effects from long-term exposure to complex mixtures, particularly at low doses, is still largely unknown. As a result, toxicological evaluations, policy, and regulations that account for chemical mixture exposure are lagging behind.

Chemical mixtures can be regulated under the current California SCP regulation. The challenges SCP faces in considering chemical mixtures are multifaceted. Challenges include: how to define mixtures for our regulatory purposes; what tools and data are available for the program to evaluate the toxicity and exposure of mixtures; how can uncertainties be estimated in evaluating the adverse impacts of chemical mixtures; what is the advantage of regulating chemical mixtures vs. single chemicals; and under what circumstances is regulating a chemical mixture appropriate and beneficial?

SCP has already observed the need to evaluate the impacts of mixtures. Alternatives evaluated for the Paint or Varnish Strippers with Methylene Chloride Priority Product will almost certainly include a mixture of chemicals as a replacement for methylene chloride. Additionally, the proposed Priority Product Nonylphenol Ethoxylates (NPEs) in Laundry Detergents uses a formulaic approach developed by other regulatory agencies to consider the potential for cumulative impacts to aquatic organisms from exposure to a mixture of NPE degradation products. Such a relatively straightforward approach is rarely available, complicating evaluation of other chemical mixtures that may result in adverse impacts to humans or the environment.

While additional discussion of the complexities of chemical mixture evaluation is certainly warranted at future GRSP meetings, the intent behind this particular discussion is to provide staff with key resources to consider in our initial work to better understand this topic. Dr. Margaret Whittaker of ToxServices LLC will be a guest panelist for this discussion. SCP staff will use recommendations from this panel discussion to conduct more research on evaluating chemical mixtures and begin to develop a process for evaluating future Priority Products and chemical substitutions.

Questions to Panel

- How is a chemical mixture practically defined in your work?
- To what extent should the SCP program consider the effects of chemical mixtures in prioritizing Priority Products and evaluating chemical substitutions? What are the benefits and challenges or knowledge gaps in considering chemical mixtures?
- What approaches to evaluate mixtures would the Panel recommend DTSC consider? Do these approaches differ when considering ecological impacts?
- What existing tools, models, and ongoing efforts for mixture evaluation would the Panel consider particularly useful for SCP?

- What regulatory frameworks exist for chemical mixture regulation and how applicable are these frameworks to the California SCP program?

Supporting Documents

- 10 - Bopp S.K. et al. 2018. Current EU research activities on combined exposure to multiple chemicals. Environment International (120) p. 544-562. https://doi.org/10.1016/j.envint.2018.07.037
- 11 - Bopp et al. 2019. Regulatory assessment and risk management of chemical mixtures: challenges and ways forward. Critical Reviews in Toxicology. https://doi.org/10.1080/10408444.2019.1579169
- 12 – Guest Speaker Profile for Dr. Margaret Whittaker, ToxServices LLC

Topic 4. Alternatives Analysis Review Process

Topic Summary

DTSC is set to receive Preliminary Alternatives Analyses (AAs) or Abridged AAs related to Paint or Varnish Strippers containing Methylene Chloride by July 1, 2019. These AAs will be the first AAs submitted under the SCP regulations. While this is an exciting milestone for the SCP Program, it also brings in to focus some of the challenges associated with evaluating AAs.

SCP regulations require review of the AA Reports within sixty (60) days. The outcome of this review will be a Notice of Compliance, Notice of Deficiency, Notice of Disapproval, or, if needed a Notice of Ongoing Review. One of the primary challenges for the AA team in reviewing these reports is complying with the short timeframe while also ensuring a quality review and informed decision-making. Without robust review, the AA process might become a mere paper exercise and could become less meaningful in advancing the development and adoption of safer alternatives. Given the comprehensive scope of AA Reports and the limited staff resources dedicated to AA review, building technical capacity and coordination of resources within the Department is critical for the AA team to succeed. The discussion will outline the potential challenges of AA review and identify some effective strategies and approaches for research, dialogue, and engagement to address these challenges. The Department will incorporate the inputs from the GRSP panel into the AA review and decision-making process.

Two presentations will provide context for discussion of this topic. First, SCP will briefly summarize the regulatory requirements for the Department in reviewing AA Reports, and the current review processes and tools that the Department has developed to date. Second, Dr. Margaret H. Whittaker from ToxServices LLC will present on their approaches and experiences in evaluating the quality of AA-related work and discuss the challenges in evaluating the quality and consistency of these studies in a short time frame.

Questions for Panel

- What methodologies, approaches, or strategies would the Panel recommend for a rapid review of an AA, while ensuring sound decision-making from the Department?
- Are there critical pieces of the Preliminary AA, Abridged AA, or Final AA Reports that the Panel would recommend focusing on reviewing, according to the review criteria in the SCP regulations (CCR section 69505.9(a))?
- What should the Department look for to ensure AAs aren't being used to excuse the continued use of a Chemical of Concern?
- In the absence of minimum data standards, what are key elements that could be used for initial screening to judge the quality of an AA?

Supporting Documents

- 3 - Pertinent Sections of the Safer Consumer Product Regulations and FSOR
- 12 - Guest Speaker Profile for Dr. Margaret Whittaker, ToxServices LLC
- 13 - Two-Stage AA Overview
- 14 - Priority Product Profile – Paint or Varnish Strippers with Methylene Chloride
- 15 - Priority Product Profile – Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates (MDI)